Evaluation of the Performance of Contour Next® and Contour Plus Elite® Blood Glucose Monitoring Systems in Arterial Blood Samples from Hospitalized Adults

Protocol/CIP: GCA-PRO-2021-004-01

Sponsor: **Ascensia Diabetes Care Australia Pty Ltd**
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Baulkham Hills, NSW 2153, Australia

[redacted] Date [redacted] Date

[redacted] Date [redacted] Date

[redacted] Date [redacted] Date

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Investigator Statement I have read this protocol and agree to ensure the conduct of the clinical performance study in accordance to the protocol as outlined I understand and agree that before seeking approval from an Ethics Review Committee, the Ascensia Diabetes Care study manager must approve any changes to the protocol. I also agree to protect the rights, safety, dignity and well-being of the participants .

Principal Investigator:	Mark Plummer, MD
Site:	Royal Adelaide Hospital , ICU Research Unit
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_____	_____	_____
PI Signature :	Printed Name:	Date:

This protocol and the data obtained from the study are confidential and may not be disclosed without the prior written consent of Ascensia Diabetes Care (ADC).

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Abbreviations

ADC	Ascensia Diabetes Care
AE	Adverse Event
ADE	Adverse Device Effect
BG	Blood Glucose
BGMS	Blood Glucose Monitoring System
CIP	Clinical Investigation Plan (Protocol)
CRF	Case Report Form
EC	Ethics Committee
EDC	Electronic Data Capture
GCP	Good Clinical Practice
HCP	Health Care Professional
ICU	Intensive Care Unit
ICF	Informed Consent Form
LAR	Legally Authorized Representative
PI	Principal Investigator
POC	Point Of Care
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SIV	Site Initiation Visit

1.0 Identification of the Protocol/ Clinical Investigation Plan (CIP)

1.1 Title of the clinical investigation: Evaluation of the Performance of Contour Next® and Contour Plus Elite® Blood Glucose Monitoring Systems in Arterial Blood Samples from Hospitalized Adults

1.2 Protocol Number: GCA-PRO-2021-004-01

1.3 Date: August 09, 2022

1.4 Revision Status

Date	Revision History
	Initial Release
	1.

2.0 Contact Information

2.1 Sponsor: Ascensia Diabetes Care Australia Pty Ltd
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CRO: Project Manager :
Gladys Williams
Labcorp Development Pty Ltd.
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2.2 PI / coordinating investigator:

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2.3 Professional position, roles, responsibilities and qualifications: ICU Medical Doctor.

2.4 Name(s) and address(es) of other institutions involved:

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97 Waterloo Road, Macquarie Park, NSW 2113, Australia

2.5 Description of study financing and the agreement between the sponsor/site.

Clinical Trial Research Agreement between Investigational Site and LabCorp.

3.0 Synopsis of the Clinical Study

Design Type:	Open Label, prospective, single arm study
Investigational Devices:	Contour Next ® Blood Glucose Monitoring System Contour Plus Elite® Blood Glucose Monitoring System
Trial objective	The purpose of the study is to extend the intended use of two BGMSs to include testing of arterial blood by Health Care Professionals (HCP) in a clinical setting. This trial will evaluate the performance of both Contour Next BGMS and Contour Plus Elite BGMS using arterial blood from adult patients hospitalized in a Critical Care Unit (medical and surgical Intensive Care Units (ICUs)). The investigational BGMS will be tested by a Point of Care (POC) operator in a clinical setting using residual arterial blood samples from adults who underwent prescribed arterial blood tests that were deemed necessary due to their medical conditions.
Reference Analyzer	Cobas c 702; Roche Diagnostics
Sample size:	A total of at least 120 blood samples tested in duplicate with at least N=240 evaluable results are required for this study. Up to 150 participants may be enrolled to obtain the required number of samples.
Inclusion and Exclusion criteria:	**Inclusion Criteria** • Patients who are at least 18 years old. • Residual Arterial blood samples collected from adult patients hospitalized in a Critical Care Unit (medical and surgical intensive care units (ICUs)). • Sample blood volume must be sufficient to complete investigational testing in addition to prescribed clinical laboratory testing.

	Exclusion Criteria • Residual arterial blood samples collected from participants previously enrolled and evaluated for this study.
Objectives and Endpoints:	The primary objective of the study is to evaluate the performance of Contour Next and Contour Plus Elite BGMSs with residual arterial blood samples. The performance of the BGMSs will be analyzed according to the following objectives: Primary Objective: • At least 95% of all blood glucose results shall fall within ±12.5% of reference values (laboratory method) for glucose concentration ≥100 mg/dL (5.55 mmol/L) and within ±12 mg/dL(±0.67 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L). • At least 98% of values should be within ±20% of reference values (laboratory method) for glucose concentration ≥75 mg/dL (4.16 mmol/L) and within ±15 mg/dL (±0.83 mmol/L) at glucose concentrations < 75 mg/dL (4.16 mmol/L).
Number of study sites	1
Proposed Start Date:	September 2022
Study Duration	Total expected duration of the clinical investigation is ~24 weeks. The residual blood sample from the participant will be tested per study procedures on the day of sample collection.

4.0 Identification and description of the investigational device

4.1 Name of the investigational device:

- Contour Next blood glucose monitoring system (Meter, Contour Next Test Strips, Control solutions)
- Contour Plus Elite blood glucose monitoring system (Meter, Contour Plus Test Strips, Control solutions)

4.2 Intended purpose of Investigational Device

4.2.1 The Contour Next and Contour Plus Elite blood glucose monitoring systems (BGMS), comprised of the blood glucose meter, the compatible test strips, and control solutions, are automated systems intended for the quantitative measurement of glucose in fresh capillary whole blood drawn from the fingertip or palm and venous blood. Its use in this clinical trial is for the quantitative measurement of glucose in arterial blood.

4.2.2 The system is intended to be used for self-testing by lay persons with diabetes and for near-patient testing by health care professionals (HCP) to monitor the effectiveness of diabetes control.

4.2.3 The BGMS can only be used for monitoring blood glucose levels and is not for diagnosis or screening of diabetes. The system is intended for in vitro diagnostic use only.

4.3 Manufacturer of the device is Ascensia Diabetes Care.

4.4 Traceability of the devices are achieved by serial numbers on the meters and lot numbers of the test strips and controls.

4.5 The population for which the device is intended in this study is critically ill patients in a hospital setting.

4.6 No contact between the devices and the patients is required since all testing will be performed on residual blood sampled from a tube.

4.7 The technical and functional features of the Investigational devices, Contour Next and Contour Plus Elite Blood Glucose Monitoring Systems, can be found in the User Guides (Attachment 1 and Attachment 2).

4.8 The instructions for use for the devices are provided in the User Guides (Attachment 1 and Attachment 2).

4.9 Training and experience required for use of the device is GCP training and laboratory experience. The study staff will be provided specific device training as part of the Site Initiation Visit (SIV) by the sponsor.

5.0 Background

Diabetes and stress hyperglycemia is very common in hospital settings and are associated with increases in hospital complications, length of stay and mortality. It is noteworthy that hypoglycaemia in hospitalized patients is also associated with poor in-patient outcomes and health-care costs. Published meta-analysis, including results of the NICE-SUGAR study, showed that intensive insulin therapy (target blood-glucose control, 80 to 110 mg/dl) was not beneficial and increased the risk of severe hypoglycemia in critically ill patients. Therefore it is important that hyperglycemia and hypoglycaemia should be avoided in hospitalized patients.

Different methods of blood glucose measurement in critically ill patients are used in daily practice, ranging from point-of-care (POC) glucose measurements with capillary or arterial blood, arterial whole blood in blood gas analyzers and to plasma or serum from venous or arterial blood measured in the central lab. Blood glucose measurements in plasma in remote central laboratory facilities of the hospital may be impractical, inefficient and unsafe to implement tight glycemic control due to the inevitable time delay between sampling and availability of the blood glucose result to the clinical staff. Methodologies for blood glucose measurements at the patient's bedside or in the ICU itself are therefore preferred from a logistical point-of-view.

In critically ill patients, having severe hemodynamics disturbance, decreased microcirculation, hypoxia for example, the only reliable source to assess vital parameters including blood glucose is arterial blood. Tight glycemic control and avoiding hypoglycemia as well as hyperglycemia in these severe patients is pivotal. It is noteworthy that a majority of these patients have complex comorbidities and are very often being treated by multiple agents (polypharmacy); therefore the performance of BGMS in their patients may be significantly different than when they are used for self-management of diabetes. Several studies have described variability in measurements made by different POC BGMSs or between these instruments and central laboratory analyzers, mainly due to the lower accuracy in the low blood glucose range and lower specificity of the enzymes used such as glucose oxidase, which make them susceptible to interference. That is why the more stringent accuracy assessment criteria for hospital-based blood glucose monitoring have been proposed by many international organizations, including the International Standardization Organization (ISO), and the Clinical Laboratory and Standards Institute (CLSI) and FDA.

6.0 Justifiation for Design of the Clinical Study

The Contour Next and Contour Plus Elite are investigational blood glucose monitoring systems (BGMS), comprised of the blood glucose meter, the compatible test strips, and control solutions. They are automated systems intended for the quantitative measurement of glucose in arterial blood, venous blood, fresh capillary whole blood drawn from the fingertip or palm. The system is intended to be used for self-testing by lay persons with diabetes and for near-patient testing by health care professionals to monitor the effectiveness of diabetes control. Alternative site testing (palm) should be done only during steady state times (when glucose is not changing rapidly). The system is intended for in vitro diagnostic use only. Its investigative use is for the quantitative measurement of glucose in arterial blood by Health Care Professionals (HCP) in a clinical setting.

This investigational clinical trial will evaluate the performance of two BGMS (Contour Next BGMS and Contour Plus Elite BGMS) using arterial blood from adult patients hospitalized in a Critical Care Unit (medical and surgical intensive care units (ICUs)). The BGMS will be used by a POC operator in a clinical setting using residual arterial blood samples from adults who underwent prescribed arterial blood tests that were deemed necessary due to their medical conditions. Only residual blood, no longer needed for clinical purposes, will be used for this study.

7.0 Risks and benefits of the investigational device and clinical investigation

Risks

This is a low risk study. Residual blood samples will ONLY be collected and tested for the study if the participant is having blood tests as prescribed by their physician and the blood is no longer needed for the patient's medical care. Therefore, there will be no additional blood samples withdrawn for this study. All testing procedures with the investigational device will be performed

by the study staff in a laboratory setting and at no point will the patient come in contact with the Investigational device or any other study related material. There is no discomfort to the patient as only residual blood will be collected.

There are no risks to patients associated with this study except for the potential for loss of confidentiality. Measures will be taken to minimize this risk by de-identifying study samples. Study samples will be assigned a number and only the participant's age and gender will be recorded. The participants initials or any other identifiable information will not be captured.

Without the identification list that is exclusively stored at the site, connection between personal data and study data is not possible.

Results of this investigational study are not intended for diagnostic purposes of the individual and are not significant for the participant's welfare. The results of the study are only intended to assess the performance of two BGM's when tested with arterial blood.

Benefits

There are no direct benefits to the participant for donation of residual blood samples for this study except to contribute to a study that provides information on the performance of two blood glucose monitoring systems when measuring glucose in arterial blood by healthcare professionals within a clinical setting.

Participants will not receive compensation for the donation of blood samples.

There are no anticipated adverse device effects.

8.0 Objectives and Hypotheses

The primary objective of the study is to evaluate the performance of Contour Next and Contour Plus Elite BGMSs with residual arterial blood samples. The performance of the BGMS will be analyzed according to the following objectives:

8.1 **Primary Objective**: The accuracy criteria below are taken from the CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013).

8.1.1 At least 95% of all blood glucose results shall fall within ±12.5% of reference values (laboratory method) for glucose concentration ≥100 mg/dL (5.55 mmol/L) and within ±12 mg/dL (±0.67 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L).

Note: Satisfying Criterion 8.1.1 would also satisfy the ISO 15917:2013 criteria of obtaining the ±15% of reference values (laboratory method) for glucose

concentration ≥100 mg/dL (5.55 mmol/L)and within ±15 mg/dL (±0.83 mmol/L) at glucose concentrations <100 mg/dL (5.55 mmol/L).

8.1.2 At least 98% of values shall be within ±20% of reference values (laboratory method) for glucose concentration ≥75 mg/dL (4.16 mmol/L) and within ±15 mg/dL (±0.83 mmol/L) at glucose concentrations < 75 mg/dL (4.16 mmol/L).

8.2 Other Objectives:

Compute differences between BGMS and laboratory blood glucose measurements and plot them against hematocrit results.

9.0 Clinical Study Design

9.1 This is an open label, prospective, single arm study. The results of the study devices will be compared to the laboratory analyzer results from the same blood sample.

9.2 For each BGMS, at least 120 evaluable samples and at least (N=240) evaluable results due to duplicate testing are required. Up to 150 participants may be enrolled to obtain the required number of samples.

9.3 Randomization:

9.3.1 Since two BGM systems will be tested in the study, the order of testing the study devices will be randomized.

9.3.2 Three strip lots (per BGMS) will be tested, with each sample tested with one lot. The strip lots will be randomized.

9.4 The results from these two BGMS systems will not be compared to each other.

9.5 The study design follows CLSI-POCT12-A3:2013; and ISO 20916:2019 (E) to ensure it is scientifically robust and valid.

9.6 Participants with non-evaluable data will be replaced as needed to obtain at least N=120 samples, and at least N=240 results (duplicate results) for each BGMS.

10.0 Investigational device(s) and comparator(s)

10.1 Materials and Methods

10.1.1 Resources Supplied by Investigator - Staffing

- Principal Investigator / and Sub-Investigators
- Healthcare professional to collect blood samples
- Site Study Staff to perform meter testing and hematocrit, and Laboratory professionals to perform laboratory analyzer testing

10.1.2 Resources Supplied by Investigator - Other

- Hospital Ethics Committee approval of the protocol
- Facility with adequate laboratory resources for conducting all tests (blood glucose laboratory analyzer, hematocrit measurement instrument)
- Facility with adequate participant population for up to 150 study-appropriate samples within the desired course of the trial
- Laboratory Analyzer, approved by the sponsor, to measure glucose in plasma. (Cobas c 702, Roche Diagnostics))
- Thermometer/hygrometers for measuring environmental conditions at the meter testing location as needed
- Print-outs of the glucose analyzer results for Quality Control (QC) checks during study days

10.1.3 Resources Supplied by Ascensia - Materials

- Protocol and sample case report forms
- Serum controls for the laboratory glucose analyzer
- CONTOUR NEXT® meters
- CONTOUR PLUS ELITE® meters
- CONTOUR NEXT® User Guide
- CONTOUR PLUS ELITE® User Guide
- CONTOUR NEXT® strips (3 lots) with inserts
- CONTOUR PLUS® strips (3 lots) with inserts
- CONTOUR NEXT® and CONTOUR PLUS® Low, Normal, and High (Levels) Control solutions with inserts
- Thermometer/hygrometers for measuring environmental conditions at the meter testing location if needed. The site may use its calibrated measuring devices with approval of Ascensia

10.2 Note that the participants will not be exposed to the study devices since residual blood samples will be collected in a tube and used for all study procedures.

10.3 All meters will have Bluetooth® ON.

10.4 The meters, test strips, and CONTOUR NEXT and PLUS control solutions must be stored at 9-30C. See Appendix C for serum control storage.

11.0 Participants

11.1 Recruitment and Enrollment

11.1.1 A minimum of 120 participants will be recruited for enrollment. Additional participants may be recruited to obtain a total of 240 evaluable results. Up to 150 participants may be enrolled to obtain the required number of samples. See section 13.8 for definition of evaluability.

11.1.2 The participant population will consist of adults who are hospitalized in a Critical Care Unit, (medical and surgical intensive care units (ICUs)) at the Investigational site.

11.1.3 Participants will be recruited from the hospitals Electronic Medical Records upon admission by the study staff.

11.1.4 If consent is required, the participant or the Legally Authorized Representative (LAR) of the Participant signs the Informed Consent Form.

11.1.5 The study staff will document participant demographics including age and gender.

11.1.6 If a participant withdraws before study start or is excluded by the Investigator, another participant could be recruited so that the validity of the study results will not be compromised.

11.1.7 Unused residual samples will be discarded according to hospital standard operational procedures.

11.2 Inclusion Criteria

11.2.1 Patients who are at least 18 years old.

11.2.2 Residual Arterial blood samples collected from participants hospitalized in a Critical Care Unit (medical and surgical intensive care units (ICUs)).

11.2.3 Sample blood volume must be sufficient to complete investigational testing procedures clinical laboratory testing.

11.3 Exclusion Criteria

11.3.1 Residual arterial blood samples collected from participants previously enrolled. and evaluated for this study.

11.4 Study Duration

11.4.1 Total expected duration to complete the clinical investigation is 24 weeks

11.4.2 The expected duration of each participant's participation is not applicable since there is no direct participant participation. Only residual blood samples from

participants will be tested per the study procedures only on the day of sample collection.

12.0 Procedures

12.1 Summary

Laboratory professionals will test the blood glucose concentration of residual arterial blood samples, collected (into a tube with anticoagulant) from participants using the Contour Next and Contour Plus Elite BGMSs. For participant's safety reasons, only residual arterial blood will be used which had been collected as prescribed for clinical testing and is no longer needed for clinical purposes.

A minimum of 120 residual arterial blood samples will be tested with both BGMSs in duplicate. Approximately 2mL of whole blood will be removed from the participant's sample tube and will be used for completing a total of 4 tests using both BGMSs (two tests with Contour Next BGMS and two tests with Contour Plus Elite BGMS), a hematocrit measurement, and duplicate laboratory glucose measurements. Each participant sample will be tested using both BGMS as per the randomization schedule. After completion of the BGMS testing, each meter will be cleaned and disinfected as per the procedures in Appendix A.

The site staff will use their Laboratory Analyzer (approved by the Sponsor) for the laboratory assessment of blood glucose samples tested in duplicate (laboratory duplicate results will be averaged).

During the study, a minimum of 10 test strip vials (50 test strips in each vial) that cover a minimum of 3 test strip lots will be used for each BGMS. The test strip lots will be randomly coded as green, blue, or red to easily identify the bottles during the study. See Table 1 for the description of test strip distribution during the study (note: the 3 test strip lots are arbitrarily designated as Red, Green, or Blue).

Blood samples will be assigned to one of three test strip lots. The assignment will be made in a rotating order following the random order in which samples are received.

The order of testing for both BGMSs will also be randomized for each sample.

Table 1 - Strip Lot Assignments Per Meter Type

Meter System & Test Strips	Green Lot	Red Lot	Blue Lot
CONTOUR NEXT Meter (CONTOUR NEXT Test Strips)	~40 Samples ~80 tests	~40 Samples ~80 tests	~40 Samples ~80 tests
CONTOUR PLUS ELITE Meter (CONTOUR PLUS Test Strips)	~40 Samples ~80 tests	~40 Samples ~80 tests	~40 Samples ~80 tests

12.2 Study Staff Training

The site study staff will participate in a training session conducted by the Ascensia Study team or designee. The training will be documented and the following will be reviewed:

12.2.1 Protocol & case report forms

12.2.2 Review of the instructions for use (UG)

12.2.3 Review of meter control solution testing

12.2.4 Error messages and troubleshooting

12.2.5 Good Clinical Practice

12.2.6 Training and practice using the Contour Next ® and Contour Plus Elite® BGMS

12.2.7 Practice preparing and reading hematocrit samples if using Ascensia hematocrit instrument

12.3 Meter Control Solution Testing

Control testing on study BGMS will occur after the meters arrive at the site and before trial starts.

12.3.1 The site staff will equally distribute the strip lots for control testing before the start of the trial.

12.3.2 The site staff will perform 3 (one each of low, normal and high) control tests on each of the CONTOUR NEXT® and CONTOUR PLUS ELITE® BGMS assigned for the study.

12.3.3 Results will be recorded and compared to the ranges for the control are listed on the test strip bottle.

12.3.4 If results are out of range, troubleshooting will be performed (see meter UGs) and the test will be repeated for a total of up to 3 attempts.

12.3.5 If the meter tests are out of range after troubleshooting is complete, the meter will be removed from the study, and Ascensia Study Manager will be notified. Additionally, this will be documented on the 'Device Deficiency Reporting Form'.

12.4 Blood Glucose Testing

12.4.1 Blood samples used for the study, approximately ~2mL, will be obtained from residual arterial blood that is drawn for prescribed testing. No blood will be taken from study participants solely for this study.

12.4.2 Samples will be collected according to hospital standards and procedures and will be collected into a tube containing anticoagulants (lithium/heparin).

12.4.3 All samples will be transported to the laboratory per standard practice and submitted for prescribed clinical testing.

12.4.4 Arterial blood samples will be inspected to verify if the volume drawn was sufficient to complete both prescribed clinical and investigational testing by laboratory personnel.

12.4.5 Samples that do not have sufficient volume to complete the required investigational testing will not be used for the clinical trial.

12.4.6 The collected samples will be used within a maximum of 5 h of sample collection time, and will be kept at room temperature (23 ± 5 °C) before evaluation.

12.4.7 If sufficient volume is available, no more than the agreed amount for each site of arterial whole blood will be removed from the original sample to perform blood glucose testing on two investigational BGMSs, laboratory analyzer, and hematocrit measurement.

12.4.8 Each blood sample will be assigned an ID that is not traceable to the identity of the participant. The first digit will indicate the site ID followed by three digits indicating the sample ID as follows: X-001, X-002, X-003, and so on.

12.4.9 Strip lot (color code) will be determined via a randomization schedule provided by the Sponsor.

12.4.10 The testing order of the meter will also be based on a randomization schedule. Note that one Contour Next and one Contour Plus Elite BGMS per participant will be used and the meters will be disinfected after use as per procedures listed in Appendix A.

12.4.11 For each participant, a CONTOUR NEXT® BGMS, and a CONTOUR PLUS ELITE® BGMS will be brought to the testing area. A test strip (as assigned for the given BGMS) will be inserted into each of the 2 meters (same color code strip lot for both meters).

12.4.12 A drop of blood will be placed on a piece of Parafilm (or other non-absorbent material) and immediately tested with the first and second meter.

12.4.13 The test strips in the two meters will then be replaced, to prepare the meters for duplicate testing.

12.4.14 A new drop of blood will be placed on the Parafilm and immediately tested with the first and second meter for duplicate testing .

12.4.15 A hematocrit measurement (%) will also be performed on the sample per site hematocrit analyzer procedures.

12.4.16 An aliquot of blood (from the same sample as used in meter testing) will be centrifuged within 10 minutes of BG testing for separation into plasma. (See Appendix B)

12.4.17 The start time of centrifugation will be recorded. Centrifugation must be performed within 10 minutes of the first-meter assay.

12.4.18 The plasma will be tested in duplicate with the laboratory analyzer within 60 minutes of the meter test. If greater than 60 minutes of the meter test, plasma samples may be refrigerated or frozen. (See Appendix B)

12.5 Errors

12.5.1 If the meter reports an error code during blood glucose testing, the instructions shown in the UG should be followed. Re-testing is recommended (per the UG). The reason for the repeated test will be documented in the comments section of the form. No more than a total of 3 attempts are allowed.

12.5.2 The study staff will record all meter error codes as appropriate for the meter tests as it occurs.

12.6 Testing Schematic

Table 2 – Sample Testing Schematic

Step	Test type	Description
1	Sample prep	▪ Ensure collection of residual Arterial sample in collection tube containing anticoagulant (lithium/heparin). ▪ Confirm sufficient blood volume to perform all testing procedures. ▪ If so, then aliquot ~2mL into microtube and cover.
2	Testing prep	Assign one CONTOUR NEXT meter and one CONTOUR PLUS ELITE meter to the patient sample. ▪ Follow the strip lot randomization (red, green, blue) and get the test strip bottle for the respective meter. ▪ Get a piece of parafilm. ▪ For steps 3 and 4, follow meter test order per randomized schedule.
3	Meter Test 1	▪ Put a test strip into each meter. ▪ Immediately place 1 drop of blood on the parafilm and test with both meters and record results. ▪ In case of error, may repeat 2 more times with a new blood drop. ▪ Record time of successful meter test.
4	Meter Test 2	▪ Replace test strips , place new drop of blood on parafilm and repeat Step 3 for duplicate testing.
5	Hematocrit	▪ Using the blood from the same collection tube, perform hematocrit measurement in accordance with site procedures. ▪ Record result.
6	Centrifugation	▪ Centrifuge blood, and record start time. (Should be within 10 min of meter tests).
7	Laboratory tests	▪ Perform blood glucose testing of plasma on laboratory analyzer in duplicate. ▪ Record results.

12.7 Accuracy and Precision of Laboratory Analyzer

- Performance of the Analyzer instruments to be used for this study will be tracked with 2 methods. The primary method will be the analyzer quality control QC check procedure regularly applied by the clinical site. In addition, serum controls will be

provided by Ascensia for internal research purposes only, and will not impact the study data or data collection. See Appendix C for further details.

12.8 Temperature and Humidity Logs

- The study staff will measure the temperature and humidity in the meter testing area once during the day that meter testing occurs and record the results on the appropriate log form.
- Study staff will maintain temperature log for the storage of investigational materials including the meters, test strips, meter controls, and serum controls.

13.0 Monitoring Plan

13.1 A monitoring plan will be completed by the Study Manager/designee prior to the study.

13.2 The study manager or designee will conduct a study initiation visit. The frequency of the number of monitoring visits by sponsor personnel or designee(s) will be based on the monitoring plan and will include at least 1-3 monitoring visits and a close-out visit.

13.3 Sponsor representatives may observe some study testing as part of study monitoring. This will be done under supervision of the Investigator.

13.4 Sponsor representatives will maintain participant confidentiality and will not interfere with the rights of human participants, safety, or bias study conduct.

14.0 Statistical Plan

14.1 Sample Size

14.1.1 The sample size requirement is based on the primary objective, section 8.0.

14.1.2 There will be a minimum of N = 120 study samples entered into the study. The meter results will be taken in duplicate, so that the total sample size of meter results will be 2*120 = 240.

14.1.3 With a sample size of n = 240 results, there is approximately a 95% chance that at least 228 of those results (95% of 240) will be "accurate" (errors within either ±12 mg/dL (±0.67 mmol/L) when the comparator result is < 100 mg/dL (5.55 mmol/L), or ±12.5% when the comparator result is ≥ 100 mg/dL (5.55 mmol/L) if the evaluation (meter) system has a 96.77% chance of yielding an "accurate" result.

14.1.4 Conversely, there is about a 95% chance of obtaining fewer than 228 "accurate" results if the system only has an approximately 92.03% chance of yielding an accurate result.

14.1.5 Note that each glucose result obtained with the evaluation devices will be considered either 'accurate' or 'not accurate, where accuracy depends on the particular test criterion as described in section 7.0 of this protocol.

14.2 Blood Glucose Measurements

Data analysis follows analyses and presentations described in the CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

14.3 Bland-Altman Plots

Modified Bland-Altman plots (the difference between each evaluation device results and reference results plotted against reference results) will be constructed.

14.4 Weighted Least Squares Regression

Weighted least squares regressions of meter results against comparator results will be performed. If *M* represents the meter result, and *C* the comparator result, the linear model can be expressed as:

$$\boldsymbol{M = \beta_0 + \beta_1 C + \varepsilon}$$

$$\boldsymbol{\varepsilon \sim N(0, cv * C)}$$

The parameter *cv* is the coefficient of variation, which is assumed to be constant across the glucose range. The weighting function will be:

$$\boldsymbol{w = C^{-2}}$$

This weighting function is used to account for the constant cv nature of glucose measurement (Draper and Smith, 1998).[1]

14.5 Accuracy Analyses

14.5.1 Two sets of metrics will be calculated:

- Relative (Percent) Difference (RD) for reference result ≥ threshold glucose :

$$\boldsymbol{RD = \frac{M - C}{C} 100\%}$$

[1] Draper, N.R., Smith, H., (1998) Applied Regression Analysis, 3rd Ed., John Wiley and Sons, New York

where: *M* =strip/meter result and *C* =comparator or reference method result.

Difference (D) for reference result < threshold glucose:

$$\boldsymbol{D = M - C}$$

14.5.2 Primary objective: The threshold glucose value is 100 mg/dL(5.55 mmol/L). Accuracy will be assessed using the Clinical and Laboratory Standards Institute (CLSI) – Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Draft Guideline-Third Edition (POCT12 (Draft 4) Vol.0 No.0 Replaces C30-A2 Vol.22 No.17).

i.e., D within ±12 mg/dL (±0.67 mmol/L) for comparator result < 100 mg/dL (5.55 mmol/L) and RD within ±12.5% for comparator result ≥ 100 mg/dL (5.55 mmol/L).

For RD, the percent of results within ±5%, ±10%, ±12.5%, ±15% and ±20% will be computed.

For *D,* the percent less than or equal to ±5 mg/dL (±0.28mmol/L), ±10 mg/dL (±0.56 mmol/L), ±12.0 mg/dL (±0.67 mmol/L), ±15 mg/dL, (±0.83 mmol/L), and ±20 mg/dL(±1.11 mmol/L)will be computed.

The *RD* and *D* distribution tables will be constructed using a threshold of 100 mg/dL (5.55 mmol/L).

As discussed in section 14.1 (Sample Size), with *n* =240, the critical number (minimum) of accurate results is 228, which yields approximately 95% chance of satisfying the criterion if the actual probability that any result will be accurate is at least 96.77%. Symbolically, this criterion is equivalent to testing the hypothesis:

$H_0 : Prob\{accurate\} < 96.77\%$ versus the alternative:
$H_1 : Prob\{accurate\} \geq 96.77\%$
This test has a power of about 95%, with n = 240, to reject H_0 if the actual probability of obtaining an accurate result is 96.77%. Conversely, there is about a 95% chance that the null will NOT be rejected if the actual probability that a result with the evaluation device would satisfy this definition of accuracy is only about 92.03%. It is possible that the sample size after the study is completed may not be exactly 240. The critical values will be approximately 95% or 98% of results (first and second parts of primary objective, respectively), and the associated hypotheses will be adjusted to reflect the change while maintaining no more than a 95% chance of rejecting the null hypotheses.

14.5.3 The second part of the primary objective states that at least 98% of the n = 240 results must fall within ±15 mg/dL(±0.83 mmol/L) of the comparator result

(comparator < 75 mg/dL/4.16 mmol/L)) or ±20% of the comparator result (comparator ≥ 75 mg/dL/4.16 mmol/L). Thus, with n = 240, there must be at least 236 BGMS results satisfying this requirement. This is equivalent to testing the hypotheses:

H_0: *Prob{accurate}*<98.33% versus the alternative:

H_1: *Prob{accurate }* ≥ 98.33%

There is approximately a 95% chance of rejecting H_0 in favor of H_1 if the actual probability that a meter measurement would satisfy the ±15mg/dL (±0.83 mmol/L) or 20% is 98.33%. Conversely, there is about a 95% chance that the null will NOT be rejected if the actual probability that a result with the evaluation device would satisfy this definition of accuracy is only about 96.23%.

14.6 Hematocrit Analysis – Other Objectives

14.6.1 Hematocrit will be measured for each participant. Mean, median, minimum, maximum, and standard deviation, will be computed for hematocrit determinations.

14.6.2 The effect of hematocrit on meter results will be presented via regression of differences between the meter and laboratory BG measurements against hematocrit.

14.7 Data Evaluability

Blood glucose data will be considered not evaluable for the following reasons:

14.7.1 Samples with no associated hematocrit value.
14.7.2 Samples with no associated (Cobas c 702)} value.
14.7.3 Failure to begin to separate the plasma from the red cells (Cobas c 702) analysis) within 10 minutes of obtaining the first meter test.
14.7.4 The collected samples are not used within a maximum of 5 h of sample withdrawal time.
14.7.5 Plasma samples that have been frozen for more than 84 days.
14.7.6 For a given sample, the meter is missing a replicate.
14.7.7 Results of the Glucose analyzer blood sample are not within ±4% of each other, 100* (Rep2-Rep1)/Rep1, or ±0.22mmol/L of each other (Rep2 – Rep1) if the average falls below 5.55mmol/L.

14.8 Means and SDs for the serum control data will be computed.

15.0 Data Management

15.1 A unique number will identify each participant/sample. The unique number will be entered on the CRFs. The site will create a procedure to de-identify participants from samples so

that the staff members documenting participant names will not have access to sample results and the staff members testing the samples will not have access to participant names. A master list of participant names, with their participant IDs, will be kept by the Investigator at the study site until the study has been closed.

15.2 Study personnel will complete and sign all appropriate forms in compliance with Good Clinical Practice (GCP). Case report forms should be completed legibly, in black or blue ink. If it is necessary to make corrections, a single line should be drawn through the original entry, the new entry is written in, and the correction initialed and dated by the individual correcting the CRF.

15.3 Study data will be primarily collected through an electronic data capture (EDC) system used by Ascensia. The data will be recorded on forms by designated study staff that will serve as source documents and entered into the EDC system. All source forms will be retained by the site.

15.4 In addition to data collection, the EDC system will be used for data cleaning as well as monitoring operations. Site users will be trained on this system before the start of the study and their access to EDC system will be contingent upon successful completion of training requirements.

15.5 The investigator/study site shall archive study documents. The investigator\/study site should take measures to prevent accidental or premature destruction of these documents. After the study has been completed, all data and documents have to be retained a minimum of three years or according to the relevant country/region regulations. Under no circumstances shall the investigator/study site relocate or dispose any study documents before having obtained written approval of the sponsor. This also applies when the archiving period expires.

16.0 Amendments to the Protocol

16.1 Any change to this protocol requires a protocol amendment (or revision) unless the IRB/EC agrees to an administrative change (for minor changes).

16.2 Determine the justification(s) for the protocol revision, impact of the changes on participant safety, the clinical or statistical significance of the data, impact of changes on the clinical investigators and their staff, and impact on timely completion of the clinical trial.

16.3 Determine if the revision meets the criteria of a Substantial Amendment.

16.4 Substantial Amendments

16.4.1 Substantial amendments to the conduct of the clinical trial may arise from changes to the protocol or from new information relating to the scientific documents in support of the trial. Substantial changes require notification to the overseeing Member State Competent Authority before implementation. For any questions on whether a change would be considered substantial, consult with the respective Member State.

16.4.2 Amendments to the trial are regarded as "substantial" where they are likely to have a significant impact on the:

- Safety, health or rights or physical or mental integrity of the participants,
- Scientific value of the trial including robustness or reliability of the data generated by the study,
- Conduct or management of the trial,
- Quality or safety of any investigational product used in the trial.

16.4.3 An amendment is only to be regarded as "substantial" when one or more of the above criteria are met but each Member State may have additional requirements that shall be considered.

16.4.4 Examples of substantial amendments may include (but are not limited to):

- New tests
- Increase in the number of visits due to safety issues associated with the ongoing trial
- Change of inclusion/exclusion criteria
- Change in the number of participants
- Updated PI / ICF
- Updated investigator brochure with relevant safety information
- Change in the management of the study
- Temporary halt to the study or restart of the trial after a temporary halt

16.5 Once justified, the protocol changes can be drafted and the changes documented in the Revision History. The changes are to be incorporated directly into the body of the protocol document itself (revised protocol).

16.6 Once the drafted revision is approved internally and by the PI, it will be submitted to the EC / IRB, where required. All subsequent, IRB/EC approved, revised protocols would be numbered sequentially.

16.7 The amended protocol will be approved by the original approvers, including the sponsor representatives or designee and the Principal Investigator(s).

16.8 The sponsor must assure that each investigator (and his/her staff) is following the most recent IRB/EC approved amendment or revised protocol as the study proceeds. The sponsor must ensure that the study monitors, investigator(s) and study staff have been trained with respect to any recent protocol amendments and revisions prior to implementation.

17.0 Deviations from the clinical protocol

17.1 A protocol deviation is any alteration or modification to the procedures described in the protocol.

17.2 The investigator is not allowed to deviate from the protocol. The only exceptions to this are:

17.2.1 The deviation is necessary to protect the participant's rights, safety and well-being, or the scientific integrity of the clinical investigation without prior approval of the sponsor and EC.

17.2.2 Prospective deviations that broaden the scope of the protocol (waivers of the protocol) are prohibited. Under emergency circumstances, these instances can proceed.

17.3 Procedures for recording, reporting and analyzing protocol deviations will include recording the deviation on a Protocol Deviation log form to be supplied by the Sponsor.

18.0 Device Accountability

18.1 Description of the procedures for the accountability of investigational devices as follows:

18.1.1 Access to investigational devices shall be controlled and the investigational devices shall be used only in the clinical investigation and according to the protocol.

18.1.2 The sponsor shall keep records to document the physical location of all investigational devices from shipment of investigational devices to the investigation sites until return or disposal.

18.1.3 Accountability: The principal investigator or a delegate shall keep records documenting the receipt, use, return and disposal of the investigational devices, (including unused, expired or malfunctioning devices) which shall include:

- Date of receipt
- Identification of each device (serial number of meter or strip lot)
- The expiry date, if applicable
- Date(s) of use

- Participant number
- Date of return of unused, expired or malfunctioning investigational devices, if applicable

All materials for this study must be stored according to the stated storage conditions and with limited access to individuals authorized by the investigator.

At the end of the clinical study, all remaining study material must be returned to the sponsor or destroyed with sponsor approval. After study completion, shipped, consumed and remaining investigational medical devices will be reconciled.

19.0 Regulatory

19.1 Ethics Committee Approval

19.1.1 Before study initiation, an Ethics Committee (EC) must review this protocol, Informed consent form (ICF) and any other supporting study documents which impact participant safety. The EC will determine if the Informed Consent is required according to local regulations and requirements or if a waiver will be obtained[2].

19.1.2 The investigational site may not begin the study until the EC has given its written and dated approval via a letter that identifies the version/date of the protocol and ICF if applicable.

19.1.3 A copy of the EC approval letter must be provided to the Investigator and to sponsor prior to the Study Initiation Visit.

19.2 Study Documentation Procedures

19.2.1 The investigator will keep study records for a minimum of three years. Alternatively, other arrangements may be made with Ascensia for study document storage.

19.2.2 Study Investigational Devices will be labeled "For Performance Evaluation Only" for this study.

19.2.3 After the study, all BGMS will be disinfected before they are returned to Ascensia. A decontamination log will be completed for the used meters. The meters, unused strip vials, control solutions, and meter User Guideswill be accounted for at the site and returned to the Ascensia Study Manager upon completion of the trial.

19.3 Investigator's Report of Study Closure

19.3.1 Sponsor representatives will notify the site that the study is closed. The study will be considered closed when the data has been locked for data analysis.

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[2] In vitro diagnostic medical devices — Clinical performance studies using specimens from human participants —Good study practice: ISO 20916:2019(E).

19.3.2 The Investigator or designee will submit a report summarizing participant disposition and other study details, as appropriate, to the Study Manager and the reviewing EC. This report will be completed within 3 months of the study closure date.

19.3.3 In addition, the Study Manager, or designee, will report the completion of the study to the EC within 6 months of study closure.

20.0 Statements of compliance

20.1 This clinical investigation will be conducted in compliance with applicable requirements:

20.1.1 Protection of Human Participants regulations in 21 CFR part 50.

20.1.2 Institutional Review Boards (IRB) regulations in 21 CFR part 56.

20.1.3 CLSI. *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline – Third Edition*. CLSI document POCT12-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

20.1.4 International Standards: ISO 20916:2019(E) – In vitro diagnostic medical devices – Clinical performance studies using specimens from human participants – Good Study Practice and In Vitro Diagnostic Regulation 2017/746 Annex XIII, Part 2.

20.1.5 Declaration of Helsinki, ICH-GCP: 2013.

20.1.6 Therapeutic Goods Act 1989 and Therapeutic Goods (Medical Device) 2002.

20.1.7 National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra British Standard: EN ISO 14155:20110 - Clinical investigation of medical devices for human participants – Good Clinical Practice.

20.1.8 British Standard BS EN 13612:2002, "Performance evaluation of in vitro diagnostic medical devices.

20.2 The clinical study shall not begin until the required approval from the EC or regulatory authority have been obtained.

20.3 Clinical trial insurance shall be provided as appropriate.

21.0 Informed Consent Process

21.1 The EC will determine if the Informed Consent is required according to local regulations and requirements for use of residual blood samples for this study.

21.1.1 Informed Consent may be waived according to requirements under the National Health and Medical Research Statement on Ethical Conduct in Human Research (2007; incorporating all updates)if the study meets all requirement for waiver as follows:

a. Involvement in the research carries no more than low risk to participants.

There is no intervention in this study. Only residual blood from routine clinical care blood assessments will be used for analysis. It involves a minimal volume of residual blood for analysis (approx. 2 mls). With appropriate measures in place to preserve participant privacy and confidentiality, collection of residual blood is a neglible/ low risk procedure. Care of participants medical condition is unaffected by the study.

b. The benefits from the research justify any risks of harm associated with not seeking consent.

This study is a low risk study due to fact that only the patient's residual blood samples are used and there is no intervention. Although there is no direct benefit to the participant research has the potential to benefit health care by providing additional information regarding a blood glucose monitoring device.

c. It is impracticable to obtain consent from participants who are considered "critically ill" and for the donation of residual blood.

The majority of participants in ICU are sedated and mechanically ventilated and it's not possible to request consent from them. Given this is only collection of residual blood sample and no intervention, with only gender and age collected, it would be onus, given what is required, to request next of kin of the participant, to provide consent. Additionally, it is truly not feasible for the researchers to conduct over 120 consents for this negligible risk study.

d. There are no known or likely reasons for thinking that participants would not have consented if they had been asked.

Given there is no intervention, and only residual blood (which would otherwise be thrown away) will be used, with minimal data (gender and age only) collected, there is no reason to believe that patients would not have consented if asked.

e. There is sufficient protection of their privacy.

Anonymised data only will be collected, specifically gender and age only.

Additionally, participants will not be identifiable from any presentations or publications arising from the research.

f. There is an adequate plan to protect the confidentiality of data.

There are no risks to patients associated with this study except for the potential for loss of confidentiality. Measures will be taken to minimize this risk by anonymising study samples. Study samples will be assigned a number and only the participant's age and gender will be recorded. The participants initials or any other identifiable information will not be captured.

g. The results have no significance for the participants' welfare and information arising from the research will be available to them on regulatory databases including Clinicaltrials.gov. and EUDAMED.

The results of the residual blood analysis will not impact on the care of participants, standard of care blood assessments (such as glucose) will be taken in addition to the residual blood samples (which will be used for study's analysis). The study will be added to Clinicaltrials.gov website.

h. There is no possibility of commercial exploitation of derivatives of the data and will not deprive the participants of any financial benefits to which they would be entitled.

There is no financial benefit to be derived from participating in this study. The study is being conducted for research purposes only.

i. The waiver is not prohibited by State, federal, or international law.

21.2 A waiver of consent is not prohibited in South Australia.

22.0 Adverse events and adverse device effects

22.1 The procedures to be performed under this protocol are considered to be of low risk since the glucose testing procedures will use residual samples which are remnants of arterial blood collected as part of routine practice and after all standard analysis has been performed.

22.2 Due to the nature of this study, no adverse events are expected as per the following:

22.3 This study only includes 'left-over samples' of blood collected by standard, approved technique for prescribed tests.

22.4 Participants will not be exposed to any of the BGMS at any point; all study activities will be conducted in the institution's lab.

22.5 Regardless of the above, any experience that the investigator considers to be an Adverse Event will be documented and reported immediately to Ascensia.

22.6 **Definition of Adverse Events**

22.6.1 Adverse Event (AE): Adverse event refers to any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury, or untoward clinical signs in participants, users, or other persons, with any connection to study related activities, whether or not related to IVD medical device under investigation.

22.6.2 Adverse Device Effect (ADE or Adverse Effect): Any adverse event resulting from insufficient or inadequate instructions for use, installation, operation, or any malfunction of the IVD medical Device under investigation. Includes any adverse event resulting from use error or from unintentional misuse of the device.

22.6.3 Serious Adverse Device Effect (SADE): Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event.

22.6.4 Serious Adverse Event (SAE): Refers to an event that led to any of the following:

- death,
- serious deterioration in the health of the participant, users or other persons as defined by one or more of the following:
  1) a life-threatening illness or injury, or
  2) a permanent impairment of a body structure or a body function including chronic diseases, or
  3) in-patient or prolonged hospitalisation, or
  4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
- fetal distress, fetal death or a congenital abnormality or birth defect including physical or mental impairment.

22.7 Adverse Event Classification

Table 3: Categories of Adverse Events (ISO 20916: 2019)

<table>
<tr><th>Adverse Events</th><th>Non -device related</th><th colspan="2">Device related</th></tr>
<tr><td></td><td>Applies to:
• Interventional Studies
• Sampling procedure causes direct harm to the participant</td><td colspan="2">Applies to:
• Interventional Studies: inaccurate test result leads to indirect harm to the participant
• Sampling procedure causes direct harm to the participant</td></tr>
<tr><td>Non-Serious</td><td>Adverse event (includes all categories)</td><td colspan="2">Adverse device effect</td></tr>
<tr><td rowspan="3">Serious</td><td rowspan="3">Serious Adverse event (includes all categories that are serious)</td><td colspan="2">Serious adverse device effect</td></tr>
<tr><td>Anticipated</td><td>Unanticipated</td></tr>
<tr><td>Anticipated Serious adverse device effect</td><td>Unanticipated Serious adverse device effect</td></tr>
</table>

22.8 Adverse Event Reporting

22.8.1 Adverse events will be documented during this study by completing the AE Form. The Investigator or designee will sign and date an AE Form for each AE that is observed.

22.8.2 AEs will be evaluated by a member of the study staff and the PI. The nature of each event and date of onset, outcome, course, maximum intensity and action taken for treatment should be established. Details of any corrective treatment should be recorded on the AE Form.

22.8.3 Investigators should follow up on the status of participants experiencing an ongoing AE until the event has been resolved, or until the condition has stabilized.

22.8.4 The Investigator or designee will notify the Study Manager or Study Monitor within 24 hours of any Serious Adverse Event that occurred during the study. Ascensia will promptly review all information relevant to the safety of the investigational device.

22.8.5 Upon the receipt of a report of an SAE by the Ascensia Study Manager or Monitor, the report will be immediately forwarded to:

Rimma Shaginian, MD, MPH Medical Director, Emerging Markets Global Medical Affairs, Ascensia Diabetes Care Email: rimma.shaginian@ascensia.com

23.0 Handling and Reporting of Device Deficiencies

23.1 Any functional problems with the investigational BGMS will be considered a device deficiency and will be documented by the study staff and timely reported to Ascensia.

23.2 The study staff should be specific about describing the problem and the sequence of events that led to it. All information will be documented on the Data Deficiency Form, including the meter type, serial number, and test strip lot.

23.3 Malfunctioning BGMs will be replaced and this will be documented for device tracking.

23.4 All device deficiencies related to the identity, quality, durability, reliability, safety or performance of an investigational medical device shall be documented throughout the clinical investigation and appropriately managed by the sponsor.

23.5 Device deficiencies that did not lead to an adverse event but could have led to a medical occurrence shall be reported to the sponsor without delay.

23.6 All device deficiencies are to be reviewed and documented in writing whether they could have led to a SADE.

24.0 Vulnerable population

24.1 While the samples will be taken from critically ill patients who are considered to be in the vulnerable population category, the procedure does not involve additional risk since the samples are residual with no additional sampling required.

24.2 If EC determines consent is required and the participants are unable to provide consent, then proxy consent by an LAR shall be provided to protect the rights of the participant.

25.0 Suspension/Premature termination and Participant Withdrawal Criteria

25.1 In the event the study is prematurely suspended or terminated, the sponsor shall be notified as well as the Ethics Committee.

25.2 The participant's sample may be withdrawn from the study at the discretion of the Investigator.

26.0 Results Handling

26.1 There is no plan for treating or following up with participants based on the investigational results from this study.

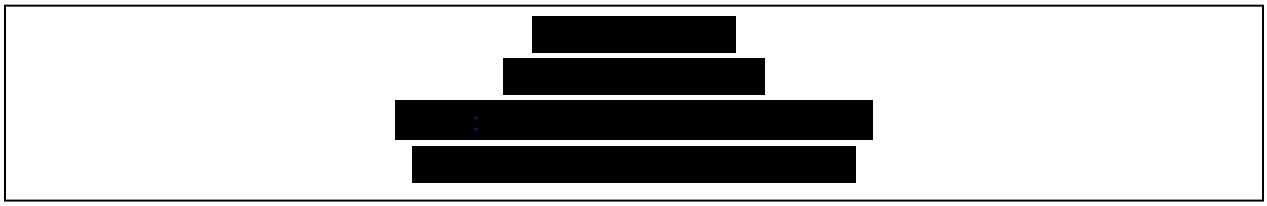
27.0 Publication policy

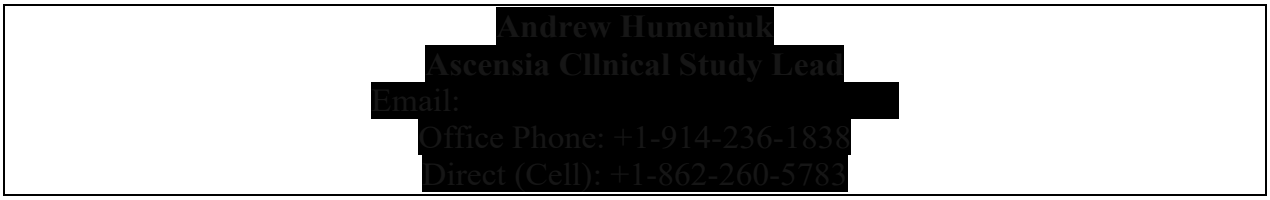
27.1 The results will be published in regulatory databases, Clinicaltrials.gov. and EUDAMED.

27.2 In general, for publication of data, the principles of Good Clinical Practice and Good Scientific Practice are respected. All manuscripts, abstracts or other modes of presentation arising from the results of the study must be reviewed and approved in writing by the sponsor in advance of submission. The sponsor's intention is neither to influence nor to prevent the publication of the study results to the medical and scientific community. The review is exclusively aimed at protecting the sponsor's proprietary information existing either at the date of commencement of the study or generated during the study. Details of the publication policy and related sponsor and principal investigator responsibilities are included in the clinical investigation agreement.

28.0 Administration

All investigator and site staff communications regarding the study should be directed to the Labcorp Study Manager. If at any time questions or problems arise concerning the evaluation, please contact the Labcorp Study Manager or the Ascensia Study Manager at the telephone number listed below.





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Appendix A- Instructions for Cleaning and Disinfecting Meters

Study staff will clean and disinfect meters according to the User Guide instructions for Health Care Professional.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility.

The following disinfection solutions are recommended; 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), didecyldimethylammonium chloride (DDAC).

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components. The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

CAUTION: Do not allow any solution to run into the meter through open areas, such as around the buttons or the meters test strip or data ports, such as USB port.

Blood glucose meters must be cleaned and disinfected by study staff before returning to Ascensia.

References

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Appendix B - Instructions for Processing Blood for Laboratory Analyzer Analysis

1. Whole blood taken via a blood gas syringe. After the arterial blood gas is processed the residual blood is transferred to a tube with anticoaguant for processing.

2. Once the residual blood tube is collected, process it as follows within 5 hours of collection:
    a. Label all tubes with the participant number using a Sharpie marker.
    b. Gently invert the blood tube several times to mix the anticoagulant.
    c. Perform the meter testing as per protocol.
    d. Within 10 minutes of first successful meter test, centrifuge the whole blood to separate the plasma from the red blood cells. Timing of all meter testing/centrifugation will be recorded on the appropriate CRF.
    e. As soon as possible after centrifugation, transfer plasma from the centrifugation tube to a micro/dispo tube or similar container. Ensure the container is labeled and the cap is secured.

3. The plasma may be refrigerated for up to 24 hours or frozen at ≤−20°C in a tightly sealed container until assayed.

4. For **refrigerated** plasma samples:
    a. Assays should be performed no later than 24 hours if refrigerated.
    b. Bring to room temperature (ambient) and invert the sample several times to ensure proper mixing.
    c. Test the sample in duplicate on the laboratory analyzer.

5. For **frozen** plasma samples:
    a. The plasma samples are stable frozen at ≤−20°C for up to 12 weeks and may be batch tested.
    b. Thaw at room temperature (ambient) and invert the sample several times to ensure proper mixing.
    c. If needed, thawed samples may refrigerated for up to 24 hours before testing.
    d. Test the sample in duplicate on the laboratory analyzer.

Appendix C - Instructions for Tracking Accuracy and Precision of Laboratory Analyzer

Procedure for Tracking Accuracy and Precision of Site Laboratory Analyzer

Performance of the Laboratory Analyzer will be assessed to ensure accuracy of the site's laboratory analyzer. Analyzer performance will be tracked by two methods: testing of the Laboratory Analyzer quality control (QC) procedure regularly applied by the clinical site for their own instrument control check process and serum controls provided by Ascensia.

The following are the procedures required for each method:

I. Laboratory Analyzer QC Procedure

The Laboratory Analyzer will be maintained and operated according to the instructions in the manufacturer's operating manual by site's lab specifications/SOP previously reviewed by ADC. Before the study begins, the analyzer will be set up and the appropriate maintenance will be performed.

The site will perform glucose analyzer control tests in accordance with the site's quality control check procedures and requirements. Site staff will keep a log for the analyzer, including daily operational checks and maintenance.

II. Ascensia Serum Controls

A set of four serum control levels will be provided to the investigator to document the performance of the (Cobas c 702, Roche Diagnostics) at each BG level. These serum controls have been assayed by a method traceable to one proposed for use as a national glucose reference method.

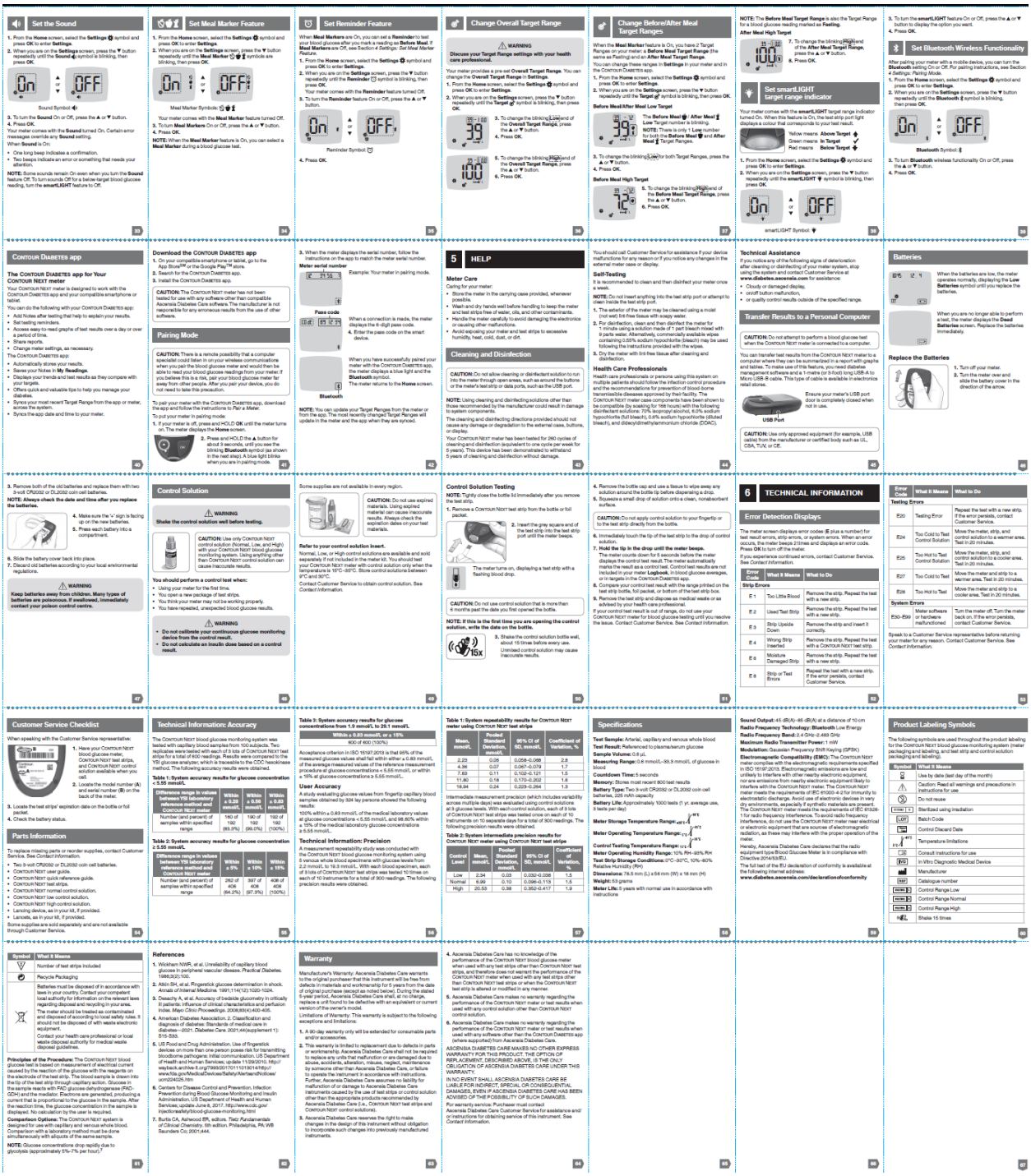
Serum Control Testing Schedule:

- Pre-study: The controls will be assayed (singlet readings) on the Laboratory Analyzer for at least three runs prior to the assay of participant samples. The runs will occur over at least three days, if possible. The data will be sent to the Ascensia Study Manager, or designee, for review before the study begins.
- Once the study begins, serum control testing should be completed on each Analyzer on a day prior and within the same week of testing plasma samples.
- Record all data on the CRF. One reading will be recorded for each control level (for a total of 4 readings per run).

Proper Handling of Ascensia Serum Controls

- Ascensia completed the characterization of serum controls purchased from Bio-Techne® (formerly Bionostics). During the characterization, staff observed that sample stratification during thawing can occur if the control vials are not handled judiciously. The recommended procedure is as follows.
    - Store the frozen controls in a -20C freezer upon arrival.
    - Thaw the frozen control amber glass vials at 2-8ºC for 2-3 days in the refrigerator. Each vial holds approximately 2.0 mL.
    - Before opening, mix the vials well by gently inverting them at least 10 times.
    - Prepare an aliquot of each level in capped microcentrifuge tubes. Cap tightly. We prefer Fisherbrand™ Microcentrifuge 0.5mL tubes (PN 02-681-333) with O-ring seal caps (PN 02-681-358).
    - Store any remaining control in the amber glass vials at 2-8ºC.
    - Before running a control sample on the laboratory analyzer, mix the aliquot tubes by gently inverting them.
    - At the beginning of each day, remix the amber glass vials and refill the aliquot tubes. When not in use, store the aliquots at 2-8ºC.
    - The thawed control use life is two weeks. Discard all thawed control—aliquot tubes and amber glass vials—after two weeks.
    - Since slow thawing for 2-3 days is recommended, it is advisable to keep an extra thawed set available for testing.

Attachment 1 - Contour Next User Guide



Set the Sound

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** 🔊 symbol is blinking, then press **OK**.

Sound Symbol 🔊

3. To turn the **Sound** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

Your meter comes with the **Sound** turned On. Certain error messages override any **Sound** setting.

When **Sound** is On:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

NOTE: Some sounds remain On even when you turn the **Sound** feature Off. To turn sounds Off for a below target blood glucose reading, turn the **smartLIGHT** feature to Off.

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Set Meal Marker Feature

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** 🍴 symbol is blinking, then press **OK**.

Meal Marker Symbols 🍴

Your meter comes with the **Meal Marker** feature turned Off.

3. To turn **Meal Markers** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

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Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see *Section 4 Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** 🔔 symbol is blinking, then press **OK**.

Your meter comes with the **Reminder** feature turned Off.

3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.

Reminder Symbol 🔔

4. Press **OK**.

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Change Overall Target Range

⚠ WARNING

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** 🎯 symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.

5. To change the blinking **High** end of the **Overall Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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Change Before/After Meal Target Ranges

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range** (the same as Fasting) and an **After Meal Target Range**.

You can change these ranges in **Settings** in your meter and in the CONTOUR DIABETES app.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** 🎯 symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target

The **Before Meal** 🍴/ **After Meal** 🍴 **Low** Target number is blinking.

NOTE: There is only 1 **Low** number for both the **Before Meal** 🍴 and **After Meal** 🍴 Target Ranges.

3. To change the blinking **Low** number for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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NOTE: The **Before Meal Target Range** is also the Target Range for a blood glucose reading marked as **Fasting**.

After Meal High Target

1. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
2. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a colour that corresponds to your test result.

Yellow means **Above Target** ⬆
Green means **In Target** ✓
Red means **Below Target** ⬇

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** 💡 symbol is blinking, then press **OK**.

smartLIGHT Symbol 💡

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3. To turn the **smartLIGHT** feature On or Off, press the ▲ or ▼ button to display the option you want.
4. Press **OK**.

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see *Section 4 Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** 🔷 symbol is blinking, then press **OK**.

Bluetooth Symbol 🔷

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button.
4. Press **OK**.

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CONTOUR DIABETES app

The CONTOUR DIABETES app for Your CONTOUR NEXT meter

Your CONTOUR NEXT meter is designed to work with the CONTOUR DIABETES app and your compatible smartphone or tablet.

You can do the following with your CONTOUR DIABETES app:

- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Change meter settings, as necessary.

The CONTOUR DIABETES app:

- Automatically stores your results.
- Saves your Notes in **My Readings**.
- Displays your trends and test results as they compare with your targets.
- Offers quick and valuable tips to help you manage your diabetes.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

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Download the CONTOUR DIABETES app

1. On your compatible smartphone or tablet, go to the App Store℠ or the Google Play™ store.
2. Search for the CONTOUR DIABETES app.
3. Install the CONTOUR DIABETES app.

CAUTION: The CONTOUR NEXT meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any erroneous results from the use of other software.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the CONTOUR DIABETES app, download the app and follow the instructions to *Pair a Meter*.

To put your meter in pairing mode:

1. If your meter is off, press and HOLD **OK** until the meter turns on. The meter displays the **Home** screen.

2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

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3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.

Meter serial number

Example: Your meter in pairing mode.

Pass code

When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.

Bluetooth

When you have successfully paired your meter with the CONTOUR DIABETES app, the meter displays a blue light and the **Bluetooth** symbol.

The meter returns to the **Home** screen.

NOTE: You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

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5 HELP

Meter Care

Caring for your meter:

- Store the meter in the carrying case provided, whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

CAUTION: Do not allow cleaning or disinfectant solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports, such as the USB port.

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your CONTOUR NEXT meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage.

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You should call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

Self-Testing

It is recommended to clean and then disinfect your meter once a week.

NOTE: Do not insert anything into the test strip port or attempt to clean inside the test strip port.

1. The exterior of the meter may be cleaned using a moist (not wet) lint-free tissue with soapy water.
2. For disinfection, clean and then disinfect the meter for 1 minute using a solution made of 1 part bleach mixed with 9 parts water. Alternatively, commercially available wipes containing 0.55% sodium hypochlorite (bleach) may be used following the instructions provided with the wipes.
3. Dry the meter with lint-free tissue after cleaning and disinfection.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility. The CONTOUR NEXT meter case components have been shown to be compatible (by soaking for 168 hours) with the following disinfectant solutions: 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), and didecyldimethylammonium chloride (DDAC).

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Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system and contact Customer Service at **www.diabetes.ascensia.com** for assistance:

- Cloudy or damaged display,
- on/off button malfunction,
- or quality control results outside of the specified range.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the CONTOUR NEXT meter is connected to a computer.

You can transfer test results from the CONTOUR NEXT meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-metre (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.

USB Port

Ensure your meter's USB port door is completely closed when not in use.

CAUTION: Use only approved equipment (for example, USB cable) from the manufacturer or certified body such as UL, CSA, TUV, or CE.

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Batteries

When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

When you are no longer able to perform a test, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries

1. Turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

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3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: Always check the date and time after you replace the batteries.

4. Make sure the '+' sign is facing up on the new batteries.
5. Press each battery into a compartment.
6. Slide the battery cover back into place.
7. Discard old batteries according to your local environmental regulations.

⚠ WARNING

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

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Control Solution

⚠ WARNING

Shake the control solution well before testing.

CAUTION: Use only CONTOUR NEXT control solution (Normal, Low, and High) with your CONTOUR NEXT blood glucose monitoring system. Using anything other than CONTOUR NEXT control solution can cause inaccurate results.

You should perform a control test when:

- Using your meter for the first time.
- You open a new package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

⚠ WARNING

- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate an insulin dose based on a control result.**

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Some supplies are not available in every region.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Refer to your control solution insert.

Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your CONTOUR NEXT meter with control solution only when the temperature is 10°C–65°C. Store control solutions between 4°C and 30°C.

Contact Customer Service to obtain control solution. See *Contact Information*.

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Control Solution Testing

NOTE: Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a CONTOUR NEXT test strip from the bottle or foil packet.

2. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

3. Shake the control solution bottle well, about 15 times before every use. Unmixed control solution may cause inaccurate results.

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4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle tip before dispensing a drop.
5. Squeeze a small drop of solution onto a clean, nonabsorbent surface.

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**

The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the CONTOUR DIABETES app.

8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your control test result is out of range, do not use your CONTOUR NEXT meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.

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6 TECHNICAL INFORMATION

Error Detection Displays

The meter screen displays error codes (**E** plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *Contact Information*.

Error Code	What It Means	What To Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a CONTOUR NEXT test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

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Error Code	What It Means	What To Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a cooler area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E30–E99	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service. See *Contact Information*.

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Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your CONTOUR NEXT blood glucose meter, CONTOUR NEXT test strips, and CONTOUR NEXT control solution available when you call.
2. Locate the model number (**A**) and serial number (**B**) on the back of the meter.
3. Locate the test strips' expiration date on the bottle or foil packet.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*.

- Two 3-volt CR2032 or DL2032 coin cell batteries.
- CONTOUR NEXT user guide.
- CONTOUR NEXT quick reference guide.
- CONTOUR NEXT test strips.
- CONTOUR NEXT normal control solution.
- CONTOUR NEXT low control solution.
- CONTOUR NEXT high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Some supplies are sold separately and are not available through Customer Service.

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Technical Information: Accuracy

The CONTOUR NEXT blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of CONTOUR NEXT test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.85 mmol/L
Number (and percent) of samples within specified range	160 of 192 (83.3%)	190 of 192 (99.0%)	192 of 192 (100%)

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI laboratory reference method and CONTOUR NEXT meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	262 of 406 (64.2%)	397 of 406 (97.8%)	406 of 406 (100%)

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Table 3: System accuracy results for glucose concentrations from 1.9 mmol/L to 29.1 mmol/L

Within ± 0.83 mmol/L or ± 15%
600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either ± 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L or within ± 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 324 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 98.60% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

Technical Information: Precision

A measurement repeatability study was conducted with the CONTOUR NEXT blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of CONTOUR NEXT test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

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Table 1: System repeatability results for CONTOUR NEXT meter using CONTOUR NEXT test strips

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.23	0.06	0.058–0.066	2.8
4.36	0.07	0.067–0.079	1.7
7.63	0.11	0.102–0.121	1.5
11.80	0.18	0.170–0.202	1.6
18.94	0.24	0.229–0.264	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 3 glucose levels. With each control solution, each of 3 lots of CONTOUR NEXT test strips was tested once on each of 10 instruments on 10 separate days for a total of 900 readings. The following precision results were obtained.

Table 2: System intermediate precision results for CONTOUR NEXT meter using CONTOUR NEXT test strips

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.34	0.03	0.032–0.038	1.5
Normal	6.99	0.10	0.094–0.113	1.5
High	20.53	0.38	0.352–0.417	1.9

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Specifications

Test Sample: Arterial, capillary and venous whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood
Countdown Time: 5 seconds
Memory: Stores most recent 800 test results
Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity
Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)

Meter Storage Temperature Range: -4°F to 158°F / -20°C to 70°C

Meter Operating Temperature Range: 50°F to 104°F / 10°C to 40°C

Control Testing Temperature Range: 50°F to 104°F / 10°C to 40°C

Meter Operating Humidity Range: 10% RH–93% RH
Test Strip Storage Conditions: 0°C–30°C, 10%–80% Relative Humidity (RH)
Dimensions: 76.5 mm (L) x 56 mm (W) x 16 mm (H)
Weight: 53 grams
Meter Life: 5 years with normal use in accordance with instructions

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Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm
Radio Frequency Technology: Bluetooth Low Energy
Radio Frequency Band: 2.4 GHz–2.483 GHz
Maximum Transmitter Power: 1 mW
Modulation: Gaussian Frequency Shift Keying (GFSK)
Electromagnetic Compatibility (EMC): The CONTOUR NEXT meter complies with the electromagnetic requirements specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the CONTOUR NEXT meter. The CONTOUR NEXT meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The CONTOUR NEXT meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the CONTOUR NEXT meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.

Hereby, Ascensia Diabetes Care declares that the radio equipment type Blood Glucose Meter is in compliance with Directive 2014/53/EU.

The full text of the EU declaration of conformity is available at the following internet address:
www.diabetes.ascensia.com/declarationofconformity

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Product Labeling Symbols

The following symbols are used throughout the product labeling for the CONTOUR NEXT blood glucose monitoring system (meter packaging and labelling, and test strip and control solution packaging and labelling).

Symbol	What It Means
	Use by date (last day of the month)
	Caution: Read all warnings and precautions in Instructions for use
	Do not reuse
STERILE R	Sterilized using irradiation
LOT	Batch Code
	Control Discard Date
	Temperature limitations
	Consult Instructions for use
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
REF	Catalogue number
CONTROL L	Control Range Low
CONTROL N	Control Range Normal
CONTROL H	Control Range High
	Shake 15 times

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Symbol	What It Means
	Number of test strips included
	Recycle Packaging
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area.
	The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment.
	Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.

Principles of the Procedure: The CONTOUR NEXT blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with PAD glucose dehydrogenase (PAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required.

Comparison Options: The CONTOUR NEXT system is designed for use with capillary and venous whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).[7]

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Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5 year period, Ascensia Diabetes Care will, at its option, repair or replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., CONTOUR NEXT test strips and CONTOUR NEXT control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

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4. Ascensia Diabetes Care has no knowledge of the performance of the CONTOUR NEXT blood glucose meter when used with any test strips other than CONTOUR NEXT test strips, and therefore does not warrant the performance of the CONTOUR NEXT meter when used with any test strips other than CONTOUR NEXT test strips or when the CONTOUR NEXT test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any control solution other than CONTOUR NEXT control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the CONTOUR NEXT meter or test results when used with any software other than the CONTOUR DIABETES app (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT, THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See *Contact Information*.

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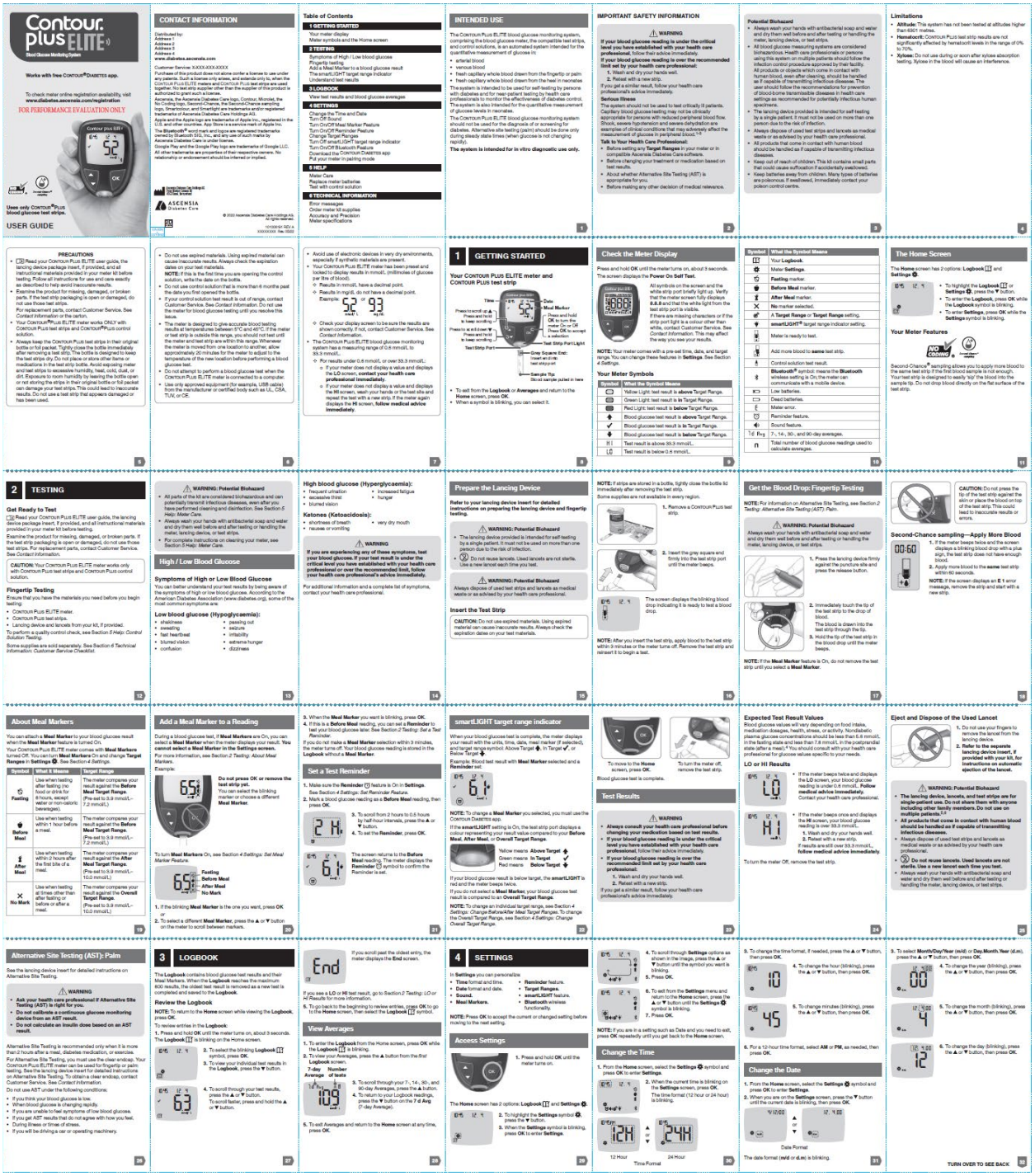
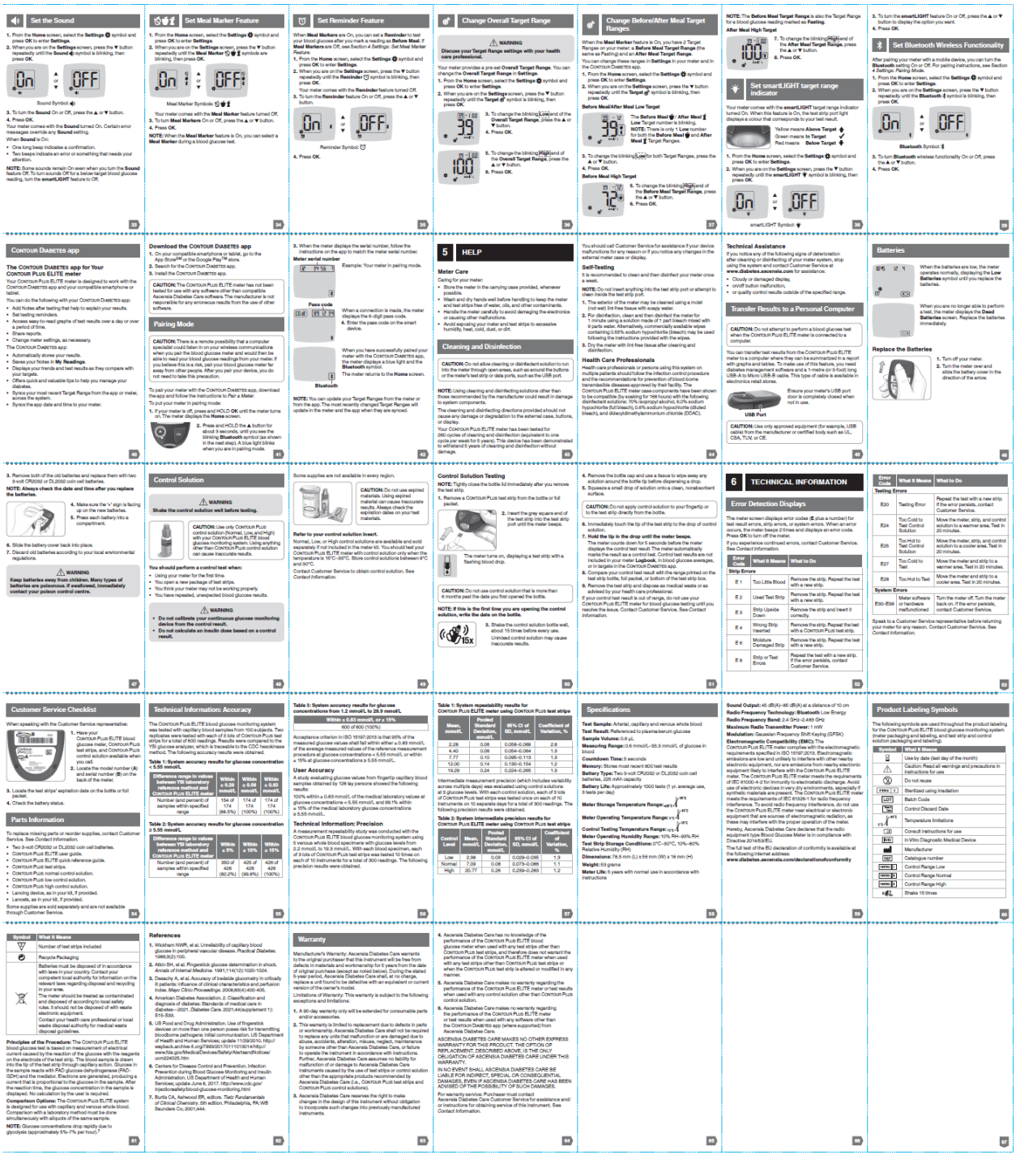
Attachment 2 – Contour Plus Elite User Guide





Set the Sound

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Sound** 🔊 symbol is blinking, then press **OK**.

On / OFF

Sound Symbol 🔊

3. To turn the **Sound** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

Your meter comes with the **Sound** turned On. Certain error messages override any **Sound** setting.
When **Sound** is On:

- One long beep indicates a confirmation.
- Two beeps indicate an error or something that needs your attention.

NOTE: Some sounds remain On even when you turn the **Sound** feature Off. To turn sounds Off for a below-target blood glucose reading, turn the **smartLIGHT** feature to Off.

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Set Meal Marker Feature

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Meal Marker** 🍽 symbol is blinking, then press **OK**.

On / OFF

Meal Marker Symbols 🍽

Your meter comes with the **Meal Marker** feature turned Off.

3. To turn **Meal Markers** On or Off, press the ▲ or ▼ button.
4. Press **OK**.

NOTE: When the **Meal Marker** feature is On, you can select a **Meal Marker** during a blood glucose test.

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Set Reminder Feature

When **Meal Markers** are On, you can set a **Reminder** to test your blood glucose after you mark a reading as **Before Meal**. If **Meal Markers** are Off, see Section *4 Settings: Set Meal Marker Feature*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Reminder** ⏰ symbol is blinking, then press **OK**.

Your meter comes with the **Reminder** feature turned Off.

3. To turn the **Reminder** feature On or Off, press the ▲ or ▼ button.

On / OFF

Reminder Symbol ⏰

4. Press **OK**.

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Change Overall Target Range

WARNING

Discuss your Target Range settings with your health care professional.

Your meter provides a pre-set **Overall Target Range**. You can change the **Overall Target Range** in **Settings**.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** ◎ symbol is blinking, then press **OK**.

3. To change the blinking **Low** end of the **Overall Target Range**, press the ▲ or ▼ button.
4. Press **OK**.
5. To change the blinking **High** end of the **Overall Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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Change Before/After Meal Target Ranges

When the **Meal Marker** feature is On, you have 2 Target Ranges on your meter: a **Before Meal Target Range** (the same as Fasting) and an **After Meal Target Range**.

You can change these ranges in **Settings** in your meter and in the Contour Diabetes app.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Target** ◎ symbol is blinking, then press **OK**.

Before Meal/After Meal Low Target

The **Before Meal** 🍴 / **After Meal** 🍴 **Low** Target number is blinking.

NOTE: There is only 1 **Low** number for both the **Before Meal** 🍴 and **After Meal** 🍴 Target Ranges.

3. To change the blinking **Low** number for both Target Ranges, press the ▲ or ▼ button.
4. Press **OK**.

Before Meal High Target

5. To change the blinking **High** end of the **Before Meal Target Range**, press the ▲ or ▼ button.
6. Press **OK**.

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NOTE: The **Before Meal Target Range** is also the Target Range for a blood glucose reading marked as **Fasting**.

After Meal High Target

7. To change the blinking **High** end of the **After Meal Target Range**, press the ▲ or ▼ button.
8. Press **OK**.

Set smartLIGHT target range indicator

Your meter comes with the **smartLIGHT** target range indicator turned On. When this feature is On, the test strip port light displays a colour that corresponds to your test result.

Yellow means **Above Target** ↑
Green means **In Target** ✓
Red means **Below Target** ↓

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **smartLIGHT** ☀ symbol is blinking, then press **OK**.

On / OFF

smartLIGHT Symbol ☀

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3. To turn the **smartLIGHT** feature On or Off, press the ▲ or ▼ button to display the option you want.
4. Press **OK**.

Set Bluetooth Wireless Functionality

After pairing your meter with a mobile device, you can turn the **Bluetooth** setting On or Off. For pairing instructions, see Section *4 Settings: Pairing Mode*.

1. From the **Home** screen, select the **Settings** ⚙ symbol and press **OK** to enter **Settings**.
2. When you are on the **Settings** screen, press the ▼ button repeatedly until the **Bluetooth** ᛒ symbol is blinking, then press **OK**.

On / OFF

Bluetooth Symbol ᛒ

3. To turn **Bluetooth** wireless functionality On or Off, press the ▲ or ▼ button.
4. Press **OK**.

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Contour Diabetes app

The Contour Diabetes app for Your Contour Plus Elite meter

Your Contour Plus Elite meter is designed to work with the Contour Diabetes app and your compatible smartphone or tablet.

You can do the following with your Contour Diabetes app:

- Add Notes after testing that help to explain your results.
- Set testing reminders.
- Access easy-to-read graphs of test results over a day or over a period of time.
- Share reports.
- Change meter settings, as necessary.

The Contour Diabetes app:

- Automatically stores your results.
- Saves your Notes in **My Readings**.
- Displays your trends and test results as they compare with your targets.
- Offers quick and valuable tips to help you manage your diabetes.
- Syncs your most recent Target Range from the app or meter, across the system.
- Syncs the app date and time to your meter.

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Download the Contour Diabetes app

1. On your compatible smartphone or tablet, go to the App Store℠ or the Google Play™ store.
2. Search for the Contour Diabetes app.
3. Install the Contour Diabetes app.

CAUTION: The Contour Plus Elite meter has not been tested for use with any software other than compatible Ascensia Diabetes Care software. The manufacturer is not responsible for any errors or results from the use of other software.

Pairing Mode

CAUTION: There is a remote possibility that a computer specialist could listen in on your wireless communications when you pair the blood glucose meter and would then be able to read your blood glucose readings from your meter. If you believe this is a risk, pair your blood glucose meter far away from other people. After you pair your device, you do not need to take this precaution.

To pair your meter with the Contour Diabetes app, download the app and follow the instructions to *Pair a Meter*.

To put your meter in pairing mode:

1. If your meter is off, press and HOLD **OK** until the meter turns On. The meter displays the **Home** screen.

2. Press and HOLD the ▲ button for about 3 seconds, until you see the blinking **Bluetooth** symbol (as shown in the next step). A blue light blinks when you are in pairing mode.

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3. When the meter displays the serial number, follow the instructions on the app to match the meter serial number.

Meter serial number

Example: Your meter in pairing mode.

Pass code

When a connection is made, the meter displays the 6-digit pass code.

4. Enter the pass code on the smart device.

When you have successfully paired your meter with the Contour Diabetes app, the meter displays a blue light and the **Bluetooth** symbol.
The meter returns to the **Home** screen.

Bluetooth

NOTE: You can update your Target Ranges from the meter or from the app. The most recently changed Target Ranges will update in the meter and the app when they are synced.

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5 HELP

Meter Care

Caring for your meter:

- Store the meter in the carrying case provided, whenever possible.
- Wash and dry hands well before handling to keep the meter and test strips free of water, oils, and other contaminants.
- Handle the meter carefully to avoid damaging the electronics or causing other malfunctions.
- Avoid exposing your meter and test strips to excessive humidity, heat, cold, dust, or dirt.

Cleaning and Disinfection

CAUTION: Do not allow cleaning or disinfectant solution to run into the meter through open areas, such as around the buttons or the meter's test strip or data ports, such as the USB port.

NOTE: Using cleaning and disinfecting solutions other than those recommended by the manufacturer could result in damage to system components.

The cleaning and disinfecting directions provided should not cause any damage or degradation to the external case, buttons, or display.

Your Contour Plus Elite meter has been tested for 260 cycles of cleaning and disinfection (equivalent to one cycle per week for 5 years). This device has been demonstrated to withstand 5 years of cleaning and disinfection without damage.

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You should call Customer Service for assistance if your device malfunctions for any reason or if you notice any changes in the external meter case or display.

Self-Testing

It is recommended to clean and then disinfect your meter once a week.

NOTE: Do not insert anything into the test strip port or attempt to clean inside the test strip port.

1. The exterior of the meter may be cleaned using a moist (not wet) lint-free tissue with soapy water.
2. For disinfection, clean and then disinfect the meter for 1 minute using a solution made of 1 part bleach mixed with 9 parts water. Alternatively, commercially available wipes containing 0.5% sodium hypochlorite (bleach) may be used following the instructions provided with the wipes.
3. Dry the meter with lint-free tissue after cleaning and disinfection.

Health Care Professionals

Health care professionals or persons using this system on multiple patients should follow the infection control procedure and the recommendations for prevention of blood-borne transmissible diseases approved by their facility. The Contour Plus Elite meter case components have been shown to be compatible (by soaking for 168 hours) with the following disinfectant solutions: 70% isopropyl alcohol, 6.0% sodium hypochlorite (full bleach), 0.6% sodium hypochlorite (diluted bleach), and didecyldimethylammonium chloride (DDAC).

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Technical Assistance

If you notice any of the following signs of deterioration after cleaning or disinfecting of your meter system, stop using the system and contact Customer Service at **www.diabetes.ascensia.com** for assistance:

- Cloudy or damaged display,
- on/off button malfunction,
- or quality control results outside of the specified range.

Transfer Results to a Personal Computer

CAUTION: Do not attempt to perform a blood glucose test when the Contour Plus Elite meter is connected to a computer.

You can transfer test results from the Contour Plus Elite meter to a computer where they can be summarized in a report with graphs and tables. To make use of this feature, you need diabetes management software and a 1-metre (or 3-foot) long USB-A to Micro USB-B cable. This type of cable is available in electronics retail stores.

Ensure your meter's USB port door is completely closed when not in use.

USB Port

CAUTION: Use only approved equipment (for example, USB cables from the manufacturer or certified body such as UL, CSA, TUV, or CE.

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Batteries

When the batteries are low, the meter operates normally, displaying the **Low Batteries** symbol until you replace the batteries.

When you are no longer able to perform a test, the meter displays the **Dead Batteries** screen. Replace the batteries immediately.

Replace the Batteries

1. Turn off your meter.
2. Turn the meter over and slide the battery cover in the direction of the arrow.

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3. Remove both of the old batteries and replace them with two 3-volt CR2032 or DL2032 coin cell batteries.

NOTE: Always check the date and time after you replace the batteries.

4. Make sure the '+' sign is facing up on the new batteries.
5. Press each battery into a compartment.
6. Slide the battery cover back into place.
7. Discard old batteries according to your local environmental regulations.

WARNING

Keep batteries away from children. Many types of batteries are poisonous. If swallowed, immediately contact your poison control centre.

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Control Solution

WARNING

Shake the control solution well before testing.

CAUTION: Use only Contour Plus control solution (Normal, Low, and High) with your Contour Plus Elite blood glucose monitoring system. Using anything other than Contour Plus control solution can cause inaccurate results.

You should perform a control test when:

- Using your meter for the first time.
- You open a new package of test strips.
- You think your meter may not be working properly.
- You have repeated, unexpected blood glucose results.

WARNING

- **Do not calibrate your continuous glucose monitoring device from the control result.**
- **Do not calculate an insulin dose based on a control result.**

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Some supplies are not available in every region.

CAUTION: Do not use expired materials. Using expired material can cause inaccurate results. Always check the expiration dates on your test materials.

Refer to your control solution insert.

Normal, Low, or High control solutions are available and sold separately if not included in the meter kit. You should test your Contour Plus Elite meter with control solution only when the temperature is 10°C–30°C. Store control solutions between 4°C and 30°C.

Contact Customer Service to obtain control solution. See *Contact Information*.

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Control Solution Testing

NOTE: Tightly close the bottle lid immediately after you remove the test strip.

1. Remove a Contour Plus test strip from the bottle or foil packet.

2. Insert the grey square end of the test strip into the test strip port until the meter beeps.

The meter turns on, displaying a test strip with a flashing blood drop.

CAUTION: Do not use control solution that is more than 6 months past the date you first opened the bottle.

NOTE: If this is the first time you are opening the control solution, write the date on the bottle.

3. Shake the control solution bottle well, about 15 times before every use. Unmixed control solution may cause inaccurate results.

15x

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4. Remove the bottle cap and use a tissue to wipe away any solution around the bottle lip before dispensing a drop.
5. Squeeze a small drop of solution onto a clean, nonabsorbent surface.

CAUTION: Do not apply control solution to your fingertip or to the test strip directly from the bottle.

6. Immediately touch the tip of the test strip to the drop of control solution.
7. **Hold the tip in the drop until the meter beeps.**
The meter counts down for 5 seconds before the meter displays the control test result. The meter automatically marks the result as a control test. Control test results are not included in your meter **Logbook**, in blood glucose averages, or in targets in the Contour Diabetes app.
8. Compare your control test result with the range printed on the test strip bottle, foil packet, or bottom of the test strip box.
9. Remove the test strip and dispose as medical waste or as advised by your health care professional.

If your control test result is out of range, do not use your Contour Plus Elite meter for blood glucose testing until you resolve the issue. Contact Customer Service. See *Contact Information*.

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6 TECHNICAL INFORMATION

Error Detection Displays

The meter screen displays error codes (E plus a number) for test result errors, strip errors, or system errors. When an error occurs, the meter beeps 2 times and displays an error code. Press **OK** to turn off the meter.

If you experience continued errors, contact Customer Service. See *Contact Information*.

Error Code	What It Means	What to Do
Strip Errors		
E 1	Too Little Blood	Remove the strip. Repeat the test with a new strip.
E 2	Used Test Strip	Remove the strip. Repeat the test with a new strip.
E 3	Strip Upside Down	Remove the strip and insert it correctly.
E 4	Wrong Strip Inserted	Remove the strip. Repeat the test with a Contour Plus test strip.
E 6	Moisture Damaged Strip	Remove the strip. Repeat the test with a new strip.
E 8	Strip or Test Errors	Repeat the test with a new strip. If the error persists, contact Customer Service.

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Error Code	What It Means	What to Do
Testing Errors		
E20	Testing Error	Repeat the test with a new strip. If the error persists, contact Customer Service.
E24	Too Cold to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E25	Too Hot to Test Control Solution	Move the meter, strip, and control solution to a warmer area. Test in 20 minutes.
E27	Too Cold to Test	Move the meter and strip to a warmer area. Test in 20 minutes.
E28	Too Hot to Test	Move the meter and strip to a cooler area. Test in 20 minutes.
System Errors		
E50–E60	Meter software or hardware malfunctioned	Turn the meter off. Turn the meter back on. If the error persists, contact Customer Service.

Speak to a Customer Service representative before returning your meter for any reason. Contact Customer Service. See *Contact Information*.

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Customer Service Checklist

When speaking with the Customer Service representative:

1. Have your Contour Plus Elite blood glucose meter, Contour Plus test strips, and Contour Plus control solution available when you call.
2. Locate the model number (**A**) and serial number (**B**) on the back of the meter.

3. Locate the test strips' expiration date on the bottle or foil packet.
4. Check the battery status.

Parts Information

To replace missing parts or reorder supplies, contact Customer Service. See *Contact Information*.

- Two 3-volt CR2032 or DL2032 coin cell batteries.
- Contour Plus Elite user guide.
- Contour Plus Elite quick reference guide.
- Contour Plus test strips.
- Contour Plus normal control solution.
- Contour Plus low control solution.
- Contour Plus high control solution.
- Lancing device, as in your kit, if provided.
- Lancets, as in your kit, if provided.

Some supplies are sold separately and are not available through Customer Service.

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Technical Information: Accuracy

The Contour Plus Elite blood glucose monitoring system was tested with capillary blood samples from 100 subjects. Two replicates were tested with each of 3 lots of Contour Plus test strips for a total of 600 readings. Results were compared to the YSI glucose analyzer, which is traceable to the CDC hexokinase method. The following accuracy results were obtained.

Table 1: System accuracy results for glucose concentration < 5.55 mmol/L

Difference range in values between YSI laboratory reference method and Contour Plus Elite meter	Within ± 0.28 mmol/L	Within ± 0.56 mmol/L	Within ± 0.83 mmol/L
Number (and percent) of samples within specified range	154 of 174 (88.5%)	174 of 174 (100%)	174 of 174 (100%)

Table 2: System accuracy results for glucose concentration ≥ 5.55 mmol/L

Difference range in values between YSI laboratory reference method and Contour Plus Elite meter	Within ± 5%	Within ± 10%	Within ± 15%
Number (and percent) of samples within specified range	350 of 426 (82.2%)	425 of 426 (99.8%)	426 of 426 (100%)

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Table 3: System accuracy results for glucose concentrations from 1.2 mmol/L to 28.9 mmol/L

Within ± 0.83 mmol/L or ± 15%
600 of 600 (100%)

Acceptance criterion in ISO 15197:2013 is that 95% of the measured glucose values shall fall within either ± 0.83 mmol/L of the average measured values of the reference measurement procedure at glucose concentrations < 5.55 mmol/L, or within ± 15% at glucose concentrations ≥ 5.55 mmol/L.

User Accuracy

A study evaluating glucose values from fingertip capillary blood samples obtained by 128 lay persons showed the following results:

100% within ± 0.83 mmol/L of the medical laboratory values at glucose concentrations < 5.55 mmol/L and 99.1% within ± 15% of the medical laboratory glucose concentrations ≥ 5.55 mmol/L.

Technical Information: Precision

A measurement repeatability study was conducted with the Contour Plus Elite blood glucose monitoring system using 5 venous whole blood specimens with glucose levels from 2.2 mmol/L to 19.3 mmol/L. With each blood specimen, each of 3 lots of Contour Plus test strips was tested 10 times on each of 10 instruments for a total of 300 readings. The following precision results were obtained.

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Table 1: System repeatability results for Contour Plus Elite meter using Contour Plus test strips

Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
2.28	0.06	0.056–0.069	2.8
4.40	0.08	0.054–0.094	1.8
7.77	0.10	0.095–0.113	1.3
12.00	0.14	0.130–0.154	1.2
19.29	0.24	0.224–0.265	1.3

Intermediate measurement precision (which includes variability across multiple days) was evaluated using control solutions at 3 glucose levels. With each control solution, each of 3 lots of Contour Plus test strips was tested once on each of 10 instruments on 10 separate days for a total of 300 readings. The following precision results were obtained.

Table 2: System intermediate precision results for Contour Plus Elite meter using Contour Plus test strips

Control Level	Mean, mmol/L	Pooled Standard Deviation, mmol/L	95% CI of SD, mmol/L	Coefficient of Variation, %
Low	2.56	0.03	0.029–0.036	1.3
Normal	7.09	0.08	0.073–0.089	1.1
High	20.77	0.26	0.239–0.283	1.2

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Specifications

Test Sample: Arterial, capillary and venous whole blood
Test Result: Referenced to plasma/serum glucose
Sample Volume: 0.6 µL
Measuring Range: 0.6 mmol/L–33.3 mmol/L of glucose in blood
Countdown Time: 5 seconds
Memory: Stores results and last results
Battery Type: Two 3-volt CR2032 or DL2032 coin cell batteries, 225 mAh capacity
Battery Life: Approximately 1000 tests (1 yr. average use, 3 tests per day)

Meter Storage Temperature Range: -40°F to 158°F / -40°C to 70°C

Meter Operating Temperature Range: 41°F to 122°F / 5°C to 50°C

Control Testing Temperature Range: 10°C–30°C

Meter Operating Humidity Range: 10% RH–90% RH
Test Strip Storage Conditions: 4°C–30°C, 10%–90% Relative Humidity (RH)
Dimensions: 76.5 mm (L) x 56 mm (W) x 16 mm (H)
Weight: 53 grams
Meter Life: 5 years with normal use in accordance with instructions

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Sound Output: 45 dB(A)–85 dB(A) at a distance of 10 cm
Radio Frequency Technology: Bluetooth Low Energy
Radio Frequency Band: 2.4 GHz–2.485 GHz
Maximum Radio Transmitter Power: 1 mW
Modulation: Gaussian Frequency Shift Keying (GFSK)
Electromagnetic Compatibility (EMC): The Contour Plus Elite meter complies with the electromagnetic requirements specified in ISO 15197:2013. Electromagnetic emissions are low and unlikely to interfere with other nearby electronic equipment, nor are emissions from nearby electronic equipment likely to interfere with the Contour Plus Elite meter. The Contour Plus Elite meter meets the requirements of IEC 61000-4-2 for immunity to electrostatic discharge. Avoid use of electronic devices in very dry environments, especially if synthetic materials are present. The Contour Plus Elite meter meets the requirements of IEC 61326-1 for radio frequency interference. To avoid radio frequency interference, do not use the Contour Plus Elite meter near electrical or electronic equipment that are sources of electromagnetic radiation, as these may interfere with the proper operation of the meter.
Hereby, Ascensia Diabetes Care declares that the radio equipment type Blood Glucose Meter is in compliance with Directive 2014/53/EU.
The full text of the EU declaration of conformity is available at the following internet address:
www.diabetes.ascensia.com/declarationofconformity

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Product Labeling Symbols

The following symbols are used throughout the product labeling for the Contour Plus Elite blood glucose monitoring system (meter packaging and labeling, and test strip and control solution packaging and labeling).

Symbol	What It Means
	Use by date (last day of the month)
	Caution: Read all warnings and precautions in instructions for use
	Do not reuse
STERILE R	Sterilized using irradiation
LOT	Batch Code
	Control Discard Date
	Temperature limitations
	Consult instructions for use
IVD	In Vitro Diagnostic Medical Device
	Manufacturer
REF	Catalogue number
CONTROL L	Control Range Low
CONTROL N	Control Range Normal
CONTROL H	Control Range High
	Shake 15 times

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Symbol	What It Means
	Number of test strips included
	Recycle Packaging
	Batteries must be disposed of in accordance with laws in your country. Contact your competent local authority for information on the relevant laws regarding disposal and recycling in your area. The meter should be treated as contaminated and disposed of according to local safety rules. It should not be disposed of with waste electronic equipment. Contact your health care professional or local waste disposal authority for medical waste disposal guidelines.

Principles of the Procedure: The Contour Plus Elite blood glucose test is based on measurement of electrical current caused by the reaction of the glucose with the reagents on the electrode of the test strip. The blood sample is drawn into the tip of the test strip through capillary action. Glucose in the sample reacts with PAD glucose dehydrogenase (PAD-GDH) and the mediator. Electrons are generated, producing a current that is proportional to the glucose in the sample. After the reaction time, the glucose concentration in the sample is displayed. No calculation by the user is required.

Comparison Option: The Contour Plus Elite system is designed for use with capillary and venous whole blood. Comparison with a laboratory method must be done simultaneously with aliquots of the same sample.

NOTE: Glucose concentrations drop rapidly due to glycolysis (approximately 5%–7% per hour).[7]

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Warranty

Manufacturer's Warranty: Ascensia Diabetes Care warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for 5 years from the date of original purchase (except as noted below). During the stated 5-year period, Ascensia Diabetes Care shall, at no charge, replace a unit found to be defective with an equivalent or current version of the owner's model.

Limitations of Warranty: This warranty is subject to the following exceptions and limitations:

1. A 90-day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to replacement due to defects in parts or workmanship. Ascensia Diabetes Care shall not be required to replace any units that malfunction or are damaged due to abuse, accidents, alteration, misuse, neglect, maintenance by someone other than Ascensia Diabetes Care, or failure to operate the instrument in accordance with instructions. Further, Ascensia Diabetes Care assumes no liability for malfunction of or damage to Ascensia Diabetes Care instruments caused by the use of test strips or control solution other than the appropriate products recommended by Ascensia Diabetes Care (i.e., Contour Plus test strips and Contour Plus control solutions).
3. Ascensia Diabetes Care reserves the right to make changes in the design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

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4. Ascensia Diabetes Care has no knowledge of the performance of the Contour Plus Elite blood glucose meter when used with any test strips other than Contour Plus test strips, and therefore does not warrant the performance of the Contour Plus Elite meter when used with any test strips other than Contour Plus test strips or when the Contour Plus test strip is altered or modified in any manner.
5. Ascensia Diabetes Care makes no warranty regarding the performance of the Contour Plus Elite meter or test results when used with any control solution other than Contour Plus control solution.
6. Ascensia Diabetes Care makes no warranty regarding the performance of the Contour Plus Elite meter or test results when used with any software other than the Contour Diabetes app (where supported) from Ascensia Diabetes Care.

ASCENSIA DIABETES CARE MAKES NO OTHER EXPRESS WARRANTY FOR THIS PRODUCT. THE OPTION OF REPLACEMENT, DESCRIBED ABOVE, IS THE ONLY OBLIGATION OF ASCENSIA DIABETES CARE UNDER THIS WARRANTY.

IN NO EVENT SHALL ASCENSIA DIABETES CARE BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF ASCENSIA DIABETES CARE HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service: Purchaser must contact Ascensia Diabetes Care Customer Service for assistance and/or instructions for obtaining service of this instrument. See *Contact Information*.

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